Annotated Bibliography of Published Health Data Interchange Standards, Describing my Personal Responsibilities and Contributions to the Respective Projects (1990-2002)

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The DICOM Standard

Digital Imaging and Communication in Medicine (DICOM). The National Electrical Manufacturers Association (NEMA). Rosslyn, VA. Cited in some jurisdictions as NEMA Standard PS3 and/or ISO Standard 12052:2006 Health informatics. Digital imaging and communication in medicine (DICOM) including workflow and data management. Published as NEMA PS3-1992, 1993, 1995, 1997; 1998; 2000; (etc).

1990-2000: Contributing author, representing the American College of Radiology. Member of the Base Standard Committee (WG6) and other working groups, founding chair of multiple working groups, editor of multiple DICOM supplements, and interdisciplinary project coordinator and technical advisor to other health data interchange standards development organizations and to professional specialty societies in the field of biomedical imaging.

Achieved full compatibility among multidisciplinary DICOM extensions; full compatibility of DICOM (Supplement 23) structured documents with the HL7 Common Document Architecture; facilitated bidirectional mapping of workflow data between HL7 and DICOM and substantially improved compatibility with other health data interchange standards. Provided 'hooks' for implementation of SNOMED, LOINC, ICD-10, BIRADS and other controlled terminologies throughout DICOM. Designed and led the development of a new generation of DICOM modules using an extensible and expressive adaptive-template/controlled-terminology structured documentation model, which influenced the development of the HL7 Common Document Architecture (CDA) and has streamlined the standards development process and enabled standard messages to be developed efficiently to represent and convey observations, inferences and procedures of any type.

The Health Level Seven (HL7) Standard

1992-2000: Contributing author, representing the American College of Radiology and the DICOM Standards Committee. Member of Technical Steering Committee. Member of the Version 3 Task Force. Founding chair of the HL7 Image Management Special Interest Group (HL7 IMSIG). Member of the HL7 SGML/XML SIG.

I believed that convergence of DICOM, SNOMED and HL7 data models (enhanced by a robust template and controlled-terminology architecture and mapped to any pertinent syntax and/or transfer protocol) was essential to achieve the critical mass of semantic infrastructure (articulated in sufficiently precise, achievable, open and forward-looking formalisms) for computerized health records to support sufficiently diverse real world use cases to reach the tipping point in the transition from physical to digital documentation of health related information. I engaged actively in multiple capacities within HL7 to accomplish necessary intermediate goals. Fred Behlen (Laitek), chair of the HL7 IMSIG, Yasser alSafadi (Philips), and Liora Alschuler (Lantana Consulting), chair of the HL7 SGML/XML SIG, mapped my structured documentation model to XML to convey image related information in the HL7 Common Document Architecture (HL7 CDA). Several patents have been granted on related technology.

SNOMED: Systematized Nomenclature of Medicine. College of American Pathologists.

1994-2002: Contributing author, technical evangelist to users and industry, and the first non-Pathologist member of the SNOMED editorial board, representing the DICOM Standards Committee. The pro-active support of CAP Vice President Pamela Cramer, and SNOMED founders Dr. Roger Coté and Dr. William Rothwell, and the personal commitment of CAP staff and committee members through the years were essential to the successful approval of DICOM color imaging, structured reporting, standardized terminology, waveform and digital mammography standards, and the capability to extend DICOM efficiently to support future extensions in diagnostic and therapeutic medical, dental and veterinary disciplines.

I organized and led a multispecialty initiative to map multi-disciplinary image-related concepts to SNOMED. Introduced robust support for SNOMED controlled terminology into the DICOM Standard. Led the development of ANSI HISPP MSDS Common Data Types for Harmonization of Communications Standards in Medical Informatics, to provide compatible data elements to convey SNOMED concepts in the prevailing health data interchange standards. Designed and curated the SNOMED/DICOM Microglossary. Introduced into the DICOM Standard and the HL7 Common Document Architecture an adaptive-template/controlled-terminology structured documentation model to streamline development of data interchange standards and optimize the precision of concept representation for any discipline needing to represent and convey observations inferences and procedures.

Clinical LOINC Codes. Logical Observation Identifiers Names and Codes. 1997.

1994-2000: Contributing author, representing the American College of Radiology and the DICOM Standards Committee. I believed LOINC was crucial to represent measurement names in DICOM, and also to achieve HL7 convergence on result reporting. I introduced LOINC into DICOM via echocardiography, and then to all areas of DICOM via a new Numeric Measurement datatype, which I had designed and specified in Supplement 23 (DICOM Structured Reporting) and other DICOM projects, such as Visible Light (color imaging), Waveforms and Digital Radiography, for that purpose.

Digital Imaging and Communications in Medicine (DICOM) Supplement 23: Structured Reporting. The National Electrical Manufacturers Association. Rosslyn, Virginia. 2000 (included in DICOM 2000).

1996-2000: Principal author and senior editor. This project was a radical departure from the ‘old’ ACR-NEMA, and became for our core development team the 'holy grail' of the multispecialty convergence initiative, refined through countless hours of technical debates through hundreds of

numbered revisions rendered in radically diverse modes of granularity, presentation style and perspective to edify and convince all stakeholders not only of the merit of the specification, but to build consensus in a voluntary, nonproprietary, quasi-legislative and highly regulated context that NEMA and a gradually broader base of stakeholders should host the development of such an audacious project, given the looming and difficult to forecast shifts of the competitive and regulatory landscape implied, from the perspective of the imaging industry, by the scope of use potentially supported by the document. Dr. David Clunie and Charles Parisot (GE Medical Systems) helped me distill my extended model into a form sufficiently constrained to pass DICOM ballot, but sufficiently robust to achieve many of the desired outcomes of the project. David authored a book entitled, "DICOM Structured Reporting," and has guided the DICOM Committee through the consideration of post-publication change-requests, which have furthered the implementation of the Standard. And, as hoped in the design phase of the original specification, a number of new DICOM SR objects for specialized use-cases have been standardized as 'parent-child' specializations of the generic model under David's guidance.

DICOM Supplement 36: Codes and Controlled Terminology. The National Electrical Manufacturers Association. Rosslyn, Virginia. Approved, 1998, and published in DICOM 1998. See PS 3.3 Section 8 and Annex D.

1995-2000: Project leader. Principal author and editor. I reasoned SNOMED was a critical-path resource that could enable unlimited downstream applications in biomedical imaging, but had very limited coverage of biomedical imaging concepts in the early 1990s. I recruited physicians, dentists and veterinarians from multiple specialties to contribute domain-specific terminology to SNOMED, and developed the codes and controlled terminology mapping resource to accelerate standards development and improve the expressivity of message standards using controlled terminology resources such as SNOMED. It was necessary to overcome industry resistance to SNOMED in the nonproprietary DICOM environment, as SNOMED was not widely known in biomedical imaging; intimidating to grasp; complex to implement (with the tools then available); and proprietary at the time I proposed it to DICOM and HL7 before SNOMED was licensed by the U.S. National Library of Medicine to facilitate

wide adoption. To achieve the necessary 'marriage' of DICOM and SNOMED it was necessary to convince the imaging industry to adopt what was initially a proprietary, complex and poorly understood resource as the favored controlled terminology of DICOM, while simultaneously negotiating with the CAP to grant concessions on licensing fees in order to achieve a mutual ‘win-win’.

ANSI HISPP MSDS Common Data Types for Harmonization of Communications Standards in Medical Informatics. ANSI HISPP Message Standards Developers Subcommittee.

The American National Standards Institute Healthcare Informatics Standards Planning Panel Message Standards Developers Subcommittee. October 30, 1993. (Reprinted in full in the Minutes of the ANSI HISPP MSDS Joint Working Group for Common Data Types. May 19, 1995. Atlanta, GA. Health Level Seven, Inc. Ann Arbor, MI. 1995.)

1992-1995: Contributing author and editor, representing the American College of Radiology, the ACR-NEMA Standards Committee and the DICOM Standards Committee. Encouraged by Bob Thompson, chair of ACR-NEMA WG8 and Charles Parisot (GE Medical Systems) to reach out to Health Level Seven (HL7) and other healthcare data interchange standards-development organizations, I targeted low-hanging fruit and pursued convergence among the organizations on common data types. We achieved sufficient consensus to justify continued support of key stakeholders and produced implementable specifications, which I introduced into DICOM throughout the draft Standard and subsequent Supplements and revisions. The early consensus and successful outcome of the Common Data Types project bought time and credibiity that allowed me to shift my focus from standards-developing organizations to clinical user groups, which I proxied by recruiting national and international professional specialty societies. The rapid and timely turnaround of this incredibly useful document with its narrow scope, universally relevant detail and the imprimature of ANSI, (barely noted by most of the participants in the plenary ANSI-HISPP 'town-hall' meetings), was a miracle that could not have occurred without the strong leadership of Dr. Clem MacDonald, chair

of the ANSI-HISPP, Rudy Mattheus, chair of European CEN TC-251 WG4 (imaging standards working group) and Charles Parisot (GE Medical Systems) respected thought-leader in the DICOM project. While still in draft form, the ANSI-HISPP consensus Common Data Types specification helped me win approval to replace the ACR-NEMA datatypes for person name, date, units of measurement and representation of coded values from controlled terminology resources such as the Systematized Nomenclature of Medicine (SNOMED) with the the common datatypes amenable to cross-standard compatibility and internationalization, and earn the support of DICOM leaders, such as Harry Solomon (Lockheed, Martin Marietta) and Larry Tarbox (Siemens), who kept my projects alive at key turning points over the years, long enough for my constituency of multi-specialty physician, dentist and veterinary stakeholders outside of ACR and NEMA to develop sufficient political power to transform the radiology-centric focus of the ACR-NEMA Standard into DICOM, capable of supporting the core attributes of multi-disciplinary image-related information needed to enable wide implementation of patient-centric health reoord systems.

SNOMED DICOM Microglossary. College of American Pathologists. Northfield, IL. 1996. Predecessor of the DICOM Terminology Mapping Resource, included in DICOM 2000, and RadLex®).

1994-2000: Designer, principal author and editor, representing the American College of Radiology, the College of American Pathologists and the DICOM Standards Committee. This document is the DICOM and SNOMED implementation of a data interchange model I developed with support from the National Library of Medicine, to optimize the expressivity and extensibility of data interchange standards constructed of small set of reusable templates that standards developers could rapidly adapt to serve new purposes by referencing appropriate subsets of concepts from controlled terminology standards, such as SNOMED, UMLS, LOINC, ICD-10, BIRADS, etc. While serving as a Visiting Scientist of the NLM and faculty member of Duke University Medical School, I used this model as a unifying motif the inter-disciplinary standards projects I was then leading in biomedical imaging. For practical and political reasons, to make the ideas accessible and relevant to the key initial stakeholders, I expressed the information model in the documentation conventions of DICOM and SNOMED. However, this particular, intentionally idiomatic example --

localized in a single real-world domain and expressed in the formalisms of [what would become, and would continue to be, after having been mapped to XML and web protocols, the] prevailing data interchange standards in that domain -- illustrates how the 'marriage' of well designed message standards and data interchange standards in this way could optimize knowledge sharing and reuse and approach theoretical full semantic fidelity in any discipline needing to represent and convey observations, inferences and procedures of any type.

DICOM Supplement 10: Basic Worklist Management (Modality Worklist Management SOP Class). The National Electrical Manufacturers Association. Rosslyn, Virginia. 1995 (included in DICOM 2000).

1993-1995: Contributing author and editor. This specification is the lynchpin of DICOM integration between imaging equipment and information systems. It specifies the protocols and data structures to convey patient-identification, imaging equipment description, imaging procedure descriptions, workflow attributes and other contextual information from imaging equipment to departmental and hospital information systems. In partnership with Don Van Sycke and Charles Parisot (GE Medical Systems) and Rudy Mattheus (CEN TC-251, WG4), I kept the project alive by convincing stakeholders to merge the overly cautious US initiative with the forward-looking European vision of standardization (contemporaneous with the formation of the European Union). Later, the European Standards Committee (CEN) and peer organizations in Japan (JIRA) and other countries became full partners with NEMA and professional specialty societies in the development and promulgation of the DICOM Standard.

DICOM Supplement 15: Visible Light Image for Endoscopy, Microscopy, and Photography. The National Electrical Manufacturers Association. Rosslyn, Virginia. 1999 (included in DICOM 2000).

1993-2000: Project leader, principal author and senior editor. I reasoned that support for color images was the 'carrot' that would attract crucial specialty groups into the DICOM project. So I established a diagnostic color image standardization initiative under the auspices of ANSI rather than NEMA, and characterized the movement as the convergence of peer professional specialty society stakeholders having mutual interest in image-

related information. With the help of Dr. James Barthel (American Society for Gastrointestinal Endoscopy), Dr. Louis Korman (ASGE), Dr. Ul Balis (College of American Pathologists) and others, I recruited peer organizations into partnership with the ACR, and convinced the ACR that the influx of peer societies into the DICOM project was an opportunity for the ACR to take a leadership role that would counterbalance the increasingly competitive incursion of other specialties into the imaging space. With the help of Gordon Bass (American College of Radiology government relations committee staff) and sympathetic staff members of the College of American Pathologists (CAP) and American Academy of Ophthalmology (AAO) and the advocacy of Dr. Steven Horii, one of the founders of ACR-NEMA and respected member of the ACR Committee for Computers, I was able to keep the project alive for several years, continually reminding the ACR, of two points: (1) that their intentional leadership in the transformation to the computerized patient record was essential to stabilize the loss of imaging revenue (from increasing competition by other specialties doing imaging procedures that in the past had been done by radiologists) and, (2) that ACR leadership would help define the role of the radiologists and the role of the ACR in the digital era.

DICOM Supplement 32: Digital X-Ray (Including Digital Mammography and Intra-oral Radiography). The National Electrical Manufacturers Association. Rosslyn, Virginia. Approved, 1998, and published in DICOM 1998. (included in DICOM 2000).

1993-2000: Contributing author. Principal author of Acquisition Context Module, Specimen Identification Module and BIRADS/SNOMED integration. The project succeeded because of the personal and professional committment of our core team of Dr. Brent Dove (American Dental Association), Dr. Ul Balis (College of American Pathologists), Dr. Lloyd Hildebrand (American Academy of Ophthalmology) and other physician leaders and staff. I was invited to provide pro-bono consultation to the American Dental Association and international dental societies on extending (ACR-NEMA) DICOM and SNOMED to dentistry. Building consensus and recruiting co-developers and ambassadors from key stakeholder groups, I was invited to provide pro-bono consultation to the CAP, AAO, ACC and others. I reasoned that Dental Radiography was an attainable and relatively uncontentious standardization target. On the other

hand, Digital Mammography, which had similar technical fundamentals and could revolutionize the field of breast cancer diagnosis, was on the verge of being approved by the FDA for breast cancer screening after years of debate, but was still hotly contested by opponents. My goal was Digital Mammography, but I could not lauch a digital mammography standard directly at the time. And other goals, such as standardization of the medical data recorded during a cardiac catheterization procedure or radiation therapy procedure, required approval of additional DICOM modules for which I needed more time to develop consensus. So, with the invaluable trust and support of Dr. Dove, I laid out a long term strategy to 'leapfrog' over highly contentious political territory by approaching the goal indirectly -- 'from bite-wings to digital mammograms' -- to avoid contentious debate causing years of delay that might fragment the industry and result in silos of proprietary formats not amenable to data mining for scientific studies and public health outcomes research in the battle against breast cancer. We achieved a fully DICOM-compatible digital mammography standard, a compatible standard for computer assisted diagnosis (CAD) data and standardized the clinical information stream flowing from cardiac catheterization procedures as spin-offs of the dental radiography project.

Trial-Use Standard for Health Care Data Interchange -- Information Model Methods: Data Model Framework. ANSI/HISPP/MSDS Joint Working Group for a Common Data Model. IEEE P1157 Medical Data Interchange Working Group. Institute of Electrical and Electronics Engineers, Inc. New York. 1994.

1992-1994: Contributing author, representing the ACR-NEMA Standards Committee and the DICOM Standards Committee. Woody Beeler (chair), Wes Rishel, Mead Walker and Abdul Malik Shakir were the lead contributors. I added the ACR-NEMA perspective, arguing for mutually compatible approaches wherever possible. The close interaction with HL7 thought-leaders here and on the HL7 Version 3 Task Force informed my HL7-DICOM convergence strategy and helped me win support from the ACR and DICOM Committee to establish the HL7 Image Management Special Interest Group (HL7 IMSIG) as the formal liaison between HL7 and DICOM, which then introduced my adaptive-template/controlled-terminology structured documentation model into the development process of the HL7 Common Document Architecture (HL7 CDA).